



ARK:jsg051007/1901048A.DEC-SKH

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Applicant : Samantha K. Holme et al.  
Serial No. : 10/719,602  
Filed : November 21, 2003  
For : COMPOSITIONS FOR REMOVING  
STAINS FROM DENTAL SURFACES  
AND METHODS OF MAKING AND  
USING THE SAME  
Examiner : Michel Graffeo  
Art Unit : 1614  
Confirmation No. : 3118  
Attorney Docket No. : (020001)-07-LAV

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I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: MAIL STOP AF, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450	
ON	May 29, 2007
NAME	Jill S. Garretson
SIGNATURE	

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

May 29, 2007

DECLARATION IN SUPPORT OF CONCEPTION AND  
REDUCTION TO PRACTICE OF INVENTION PRIOR TO MARCH 19, 2001

Dear Sir:

I, Samantha K. Holme, declare and say as follows:

1. I am one of the principal inventors of the subject matter of the above-identified patent application U.S. Serial No. 10/719,602 filed November 21, 2003.

2. Based on information and belief, the claims of the present application are directed to a chewing gum composition for removing stains from dental surfaces which includes a gum base and at least two stain removing components. The stain removing components are selected from a peroxide compound, a polyphosphate and an anionic surfactant. A preferred aspect of the invention provides that the selected stain removing components are not mixed directly with the gum base so that the stain removing components are not materially bound to the gum base and are therefore better able to perform their stain removing function.

3. Attached to this Declaration as Exhibit A is a document entitled, "Batch Sheets for year 2000". Batch Sheets are listings (hereinafter, "Batch Sheet Listings") of particular experiments that were performed in the Warner Lambert Company chewing gum lab. The Batch Sheet Listing includes the Batch Number which is a five digit number beginning with the first experiment of the year 2000 have number 0-0001. The Batch Sheet Listing also includes a brief identification of the experiment, the person who performed and/or supervised the experiment identified by the person's initials, and the date of the experiment. The recordation of the Batch Sheet Listings was a required policy of Warner-Lambert Company and the completion of the Batch Sheet Listings was carried out in accordance with the required policy.

4. In addition and in accordance with required policy, the person in charge of each experiment referred to in the Batch Sheet Listing was required to prepare or have prepared a Batch Sheet as shown in Exhibit B. Each Batch Sheet shows the name of the ingredients used in the experiment, the date of the experiment and the person who performed or supervised the experiment. In addition, the method employed in conducting the experiment was to be provided under the title, "Procedure".

5. It was also the required policy of Warner-Lambert Company to maintain notebooks for the concurrent recordation of Batch Sheet Listings and to provide Batch Sheets to provide detailed information of the experiments corresponding to the Batch Sheet Listings. Based on information and belief, the Batch Sheet Listings of Exhibit A and the Batch Sheets of Exhibit B accurately reflect the experiments that were conducted and the dates that the experiments were conducted.

6. Batch Sheet Listing No. 0-0300 was prepared by me and identified an experiment in which a chewing gum composition was prepared on August 18, 2000 by me or under my direct supervision and control as evidenced by my initials "SKH". The experiment was identified by the designation 1.0% by weight of STP (sodium tripolyphosphate) and 1% by weight of carbamide peroxide which are stain removing agents employed in the above-identified patent application. The corresponding Batch Sheet No. 0-0300 (see Exhibit B) also shows my initials and the same date August 18, 2000. The Batch Sheet No. 0-0300 shows the use of twelve ingredients

to prepare a chewing gum composition. Ingredient Nos. 1-3 are gum base ingredients. Ingredient Nos. 3-12 are non-gum base ingredients. Of particular interest are ingredient No. 11 (carbamide peroxide) and ingredient No. 12 (sodium tripolyphosphate) each in amounts of 1.33% by weight. The listing of ingredient Nos. 11 and 12 is indicative that both stain removing agents were used in the thus prepared chewing gum composition and the amount is consistent with the amount of each ingredient identified in Batch Sheet Listing No. 0-0300.

7. The method of preparing the chewing gum composition of Batch Sheet No. 0-0300 is shown at the bottom of the Batch Sheet under the heading, "Procedure". After addition of molten gum base to the kettle, the remaining materials were sequentially added including sorbitol, mannitol, sweeteners and flavors. Thereafter, the carbamide peroxide and sodium tripolyphosphate were added. Thus, to the best of my knowledge and as supported by Batch Sheet No. 0-0300, the stain removing agents were not mixed directly with the gum base.

8. Batch Listing No. 0-0321 was prepared by me and identifies an experiment in which a chewing gum composition was prepared on August 30, 2000 by me or under my direct supervision and control as evidenced by my initials "SKH". The Batch Listing No. 0-0321 identifies the experiment by the designation 3% by weight carbamide peroxide and 0.5% by weight of sodium stearate which are stain removing agents employed in the above-identified patent application. The corresponding Batch Sheet No. 0-0321 shows the use of twelve ingredients to

prepare a chewing gum composition. Ingredient Nos. 1-3 refer to gum base ingredients while ingredient Nos. 3-12 are non-gum base ingredients. Ingredient No. 11 (sodium stearate) and ingredient No. 12 (carbamide peroxide) in amounts of 0.5% by weight and 3.99% by weight, respectively are indicative that both stain removing agents were used in the thus prepared chewing gum composition and the amounts are consistent with the amount of each ingredient in Batch Sheet Listing No. 0-0321.

9. The method of preparing the chewing gum composition of Batch Sheet No. 0-0321 is shown at the bottom of the Batch Sheet under the heading, "Procedure". After addition of molten gum base to the Kettle, the remaining materials were sequentially added including sorbitol, mannitol, sweeteners and flavors. Thereafter, the sodium stearate and carbamide peroxide were added. Thus, to the best of my knowledge and as supported by Batch Sheet No. 0-0321, the stain removing agents were not mixed directly with the gum base.

10. Batch Listing No. 0-0322 was prepared by me and identifies an experiment in which a chewing gum composition was prepared on August 30, 2000 by me or under my direct supervision and control as evidenced by my initials "SKH". The Batch Listing No. 0-0322 identifies the experiment as by the designation 3% by weight carbamide peroxide and 3.0% by weight of sodium tripolyphosphate which are stain removing agents employed in the above-identified patent application. The corresponding Batch Sheet No. 0-0322 (see Exhibit B) also shows my initials and the same date, August 30, 2000. The Batch Sheet No. 0-0322 shows the use of twelve

ingredients to prepare a chewing gum composition. Ingredient Nos. 1-3 refer to gum base ingredients while ingredient Nos. 3-12 are non-gum base ingredients. Ingredient No. 11 (sodium tripolyphosphate) and ingredient No. 12 (carbamide peroxide) each in amounts of 3.99% by weight are indicative that both stain removing agents were used in the thus prepared chewing gum composition.

11. The method of preparing the chewing gum composition is shown at the bottom of the Batch Sheet No. 0-0322 under the heading, "Procedure". After addition of molten gum base to the kettle, the remaining materials were sequentially added including sorbitol, mannitol, sweeteners and flavors. Thereafter, the sodium stearate and carbamide peroxide were added. Thus, to the best of my knowledge and as supported by Batch No. 0-0322, the stain removing agents were not mixed directly with the gum base.

12. The chewing gum formulations corresponding to Batch Listing Nos. 0-0300, 0-0321 and 0-0322 were tested by me or under my direct supervision to determine their ability to remove stains from bovine teeth over the course of a simulated seven days of chewing. The tests were performed at Indiana – Purdue University. Attached hereto as Exhibit C is an e-mail dated January 17, 2001 from myself to my co-inventor, Shiuh Luo reporting the results of the tests. Also forming part of Exhibit C is a graph showing the results reported to Shiuh Luo on January 17, 2001.

13. Based on information and belief, the testing of stain removing properties was conducted in an art recognized protocol for measuring stain reduction and all compositions were tested in the same manner using the same protocol.

14. As shown in Exhibit C, the chewing gum composition identified as 1% carbamide peroxide/1% STP corresponds to Batch Listing No. 0-0300. The chewing gum composition identified as 3% carbamide peroxide/0.5% Na stearate corresponds to Batch Listing No. 0-0321 and the chewing gum composition identified as 3% carbamide peroxide/3% STP corresponds to Batch Listing No. 0-0322. Each of the compositions were tested for stain reduction over a simulated seven days of chewing for all bovine teeth and bottom bovine teeth. Each of the compositions utilizing two stain removing ingredients exhibit significant stain removing reductions.

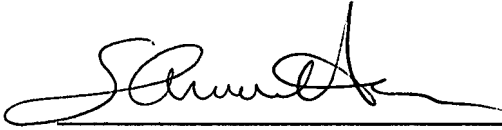
15. Based on information and belief, the information present herein in Exhibits A-C accurately reflects the work performed in making and assessing chewing gum compositions containing two stain removing agents in accordance with the above-identified application. Other records may have been generated at the time the chewing gum compositions were made and assessed including laboratory notebooks and invention records which were required by Warner Lambert Company at the time the work was performed. It is my understanding that a diligent search has been conducted to locate these records but they have not been found. It is also my understanding that the reasons the records cannot be located include misplacement when the records were transferred from the Warner Lambert

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Company to Pfizer to the current owner of the above-identified patent application, Cadbury Adams USA LLC and/or records were destroyed when a Cadbury Adams USA LLC facility believed to contain such documents suffered significant water damage.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: May 23, 2007

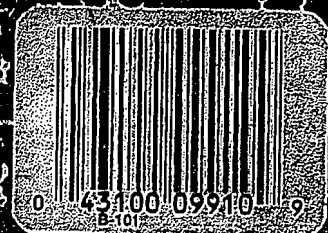
  
Samantha K. Holme



**Mead**  
**COMPOSITION**  
*Batch Sheets For*  
*Year 2000*

100 sheets • 200 pages  
9<sup>3</sup>/<sub>4</sub> x 7<sup>1</sup>/<sub>2</sub> in/24.7 x 19.0 cm  
wide ruled • 09910

© 1994 — The Mead Corporation, Dayton, Ohio 45463 U.S.A. Made in U.S.A.



for (improved surfactant gum)

0-0293 Trident Advantage Blank Gum BJB 8-17-00

0-0294 Bubblicious Salpicon .04 200g. batch KISHOR 8-17

0-0295 Bubblicious Salpicon .12

0-0296 T.A. E 0.5% Na<sup>+</sup> Stearate in core - I.P. SKH 8/18/00

0-0297 T.A. E 0.5% Na<sup>+</sup> Stearate / 3% STP in core - I.P. SKH 8/18/00

0-0298 T.A. E 3.0% Na<sup>+</sup> Stearate in core - I.P. SKH 8/18/00

0-0299 T.A. E 1.0% Carbamide Peroxide - I.P. SKH 8/18/00

0-0300 T.A. E 1.0% STP / 1% Carbamide Peroxide - I.P. SKH 8/18/00

0-0301 T.A. E 3.0% Carbamide Peroxide in core - I.P. SKH 8/18/00

0-0302 Bubblicious Salpicon Orange, <sup>code 382</sup> Banana, Strawberry I.P. 8/21/00

0-0303 (G-00-12 gum) } comp 6 improvement } Lunal 8/27/00

0-0304 (G-00-13 gum) }

0-0305 (G-00-14 gum) }

0-0306 (G-00-15 gum) }

0-0307 Bubblicious Salpicon Orange <sup>code 799</sup> Banana Strawberry E. 8/21

0-0308 TRIDENT Cappuccino Control AS 8-22

0-0309 TRIDENT " " A.G. 8-22

0-0310 Collection - Tropical Rum Punch M.B. 8-22

0-0311 " " " " " " ↓ ↓

0-0312 Trident Blank Gum BJB 8/23/00

0-0313 Trident slab E Gv. encap >509 590 μ SKH 8/28/00

0-0314 " " C " " >425 <590 μ SK 8/28/00

0-0315	Improvement of Comp 6 NSBR CG-00-16 gum	Kunal	08/24/00
0-0316	Trident Advantage w/surfactant	BJB	08/30/00
0-0317	" " "	"	"
0-0318	" " "	"	"
0-0319	" " "	"	"
0-0320	Trident Spearment <sup>(in-house)</sup> encaps. Inhibitor 370	SKA	8/30/00
0-0321	T.A. & 3% Carbam. de Perox. de / 0.5% Nat Stearate	SKA	8/30/00
0-0322	TA & 3% Carbam. de Perox. de / 3% STP	SKA	8/30/00
0-0323	Trident Advantage Control Pppt	BJB	9/1/00
0-0324	" " " Coolmint	BJB	9/1/00
0-0325	Trident Advantage Placebo w/clinure	BJB	9/6/00
0-0326	Certs Terminator	Specimen	9/8/00
0-0327	Certs Terminator	"	9-8-2000
0-0328	Certs Terminator	"	9-8-2000
0-0329	Certs Terminator	"	9-8-2000
0-0330	Certs "	"	9-8-2000
0-0331	Certs "	"	9-8-2000
0-0332	Improvement of Comp 6 NSBR CG-00-17 gum	Kunal	9/12/2000
0-0333	Comp 16 improvement C16-001 a gum	Kunal	"
0-0334	" " " C16-002 gum	Kunal	"
0-0335	Trident Slab & encaps Nat Stearate <sup>more</sup> (in-house)	SKA	9/15/00

**NOTEBOOK #:**

PROJECT NAME: <b>Tooth Whitening</b>		PROJ. NUM.: <b>97065</b>	
COMMENTS: Based on clinical formula W015884-43S with 1% carbamide peroxide/1% STP for Indiana-Purdue study			
FLAVOR: <b>Peppermint</b>		REF.:	IPR:
SHBET DATE:	<b>18-Aug-00</b>	PREP. BY: <b>S. Holme</b>	SIGNED & UNDERSTOOD BY:
BATCH NUM: <b>0-0300</b>		LAB #:	BATCH SIZE, g: <b>2500</b>
LOT NUM:		KETTLE #:	

[illegible]

DISPOSITION	FORM	WEIGHT	LENGTH	DIMENSIONS	
				WIDTH	THICKNESS
Lab Dev. Batch	Pellet	0.94g (uncoated)			
		1.42g (coated)	0.663"	0.516"	0.251"

**PROCEDURE:**

Into a clean, dry and warmed kettle...

1. Add molton gum base to kettle.
2. Add 1/3 of sorbitol and all mannitol, 3 minutes forward.
3. Add remaining sorbitol and start mixing in forward for 3 min.
4. Add a blend of sweeteners and flavors and then sodium stearate, mix 3F
5. Discharge, roll and score

*(Carbamide granules / 500g)*

	MAX	ACTUAL
CUSH TEMP. BEFORE ENCAP:		
	MAX	ACTUAL
DROP TEMP		
	MAX	ACTUAL
MADE BY.		
DATE		

## GUM LAB BATCH SHEET

**NOTEBOOK #:**

PROJECT NAME: Tooth Whitening		PROJ. NUM.: 97065	
COMMENTS: Based on clinical formula W015884-43S with 0.5% sodium stearate and 3% carbamide peroxide			
FLAVOR: Peppermint		REF.:	IP#:
SHEET DATE:	31-Aug-00	PREP. BY: S. Holmes	SIGNED & UNDERSTOOD BY:
BATCH NUM: 0-0321	LAB #:		BATCH
LOT NUM:	KETTLE #:		SIZE, g: 2500

[illegible]

<u>DISPOSITION</u>	<u>FORM</u>	<u>WEIGHT</u>	<u>DIMENSIONS</u>		
Lab Dev. Batch	Pellet	0.94g (uncoated)	LENGTH	WIDTH	THICKNESS
		1.42g (coated)	0.663"	0.516"	0.251"

PROCEDURE:

Into a clean, dry and warmed kettle...

1. Add molton gum base to kettle.
2. Add 1/3 of sorbitol and all mannitol, 3 minutes forward.
3. Add remaining sorbitol and start mixing in forward for 3 min.
4. Add a blend of sweeteners and flavors and then sodium stearate and carbamide peroxide, mix 3F
5. Discharge, roll and score

MAX.	ACTUAL
GUM TEMP. BEFORE ENCAP.	
MAX.	ACTUAL
DROP TEMP.	
MAX.	ACTUAL
MADE BY:	
DATE:	



Subj: **FW: RE: U.S. Patent Application No. 10/719,602/W/L Reference No.: (020001)-07-LAV, Your reference: 190.1.048 A**  
Date: 4/30/2007 5:07:23 P.M. Eastern Daylight Time  
From: [Jianping.Chao@cs-americas.com](mailto:Jianping.Chao@cs-americas.com)  
To: [WKAAllen1@aol.com](mailto:WKAAllen1@aol.com)

2 of 2.

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**From:** Holme, Samantha  
**Sent:** Friday, April 20, 2007 11:54 AM  
**To:** Chao, Jianping  
**Subject:** FW: IP Results

Jianping,

Here's some in-vitro data, conducted at Indiana-Purdue University using whole gum formulations.

Samantha

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**From:** Holme, Samantha  
**Sent:** Wednesday, January 17, 2001 4:46 PM  
**To:** Luo, Shiuh  
**Subject:** IP Results

Shiuh,

Attached are the summary results of the 2 studies we ran at IP. The results are fairly consistent with one another, however I'm concerned with the Trident Advantage results. It performed the worst out of all the prototypes, including Dentyne Ice and are lower than previous test results done using the same method. But the Dentyne Ice results are consistent with past results. There doesn't seem to be much difference in efficacy between 3% Carbamide peroxide/3% STP and 1% Carbamide peroxide/1% STP. These two prototypes performed best. I was not surprised by the lower results for the sodium stearate alone, since this is the first time we've tested it in the core in this model. The sodium stearate results are consistent with the clinical results. We can draw an indication from these results that the carbamide peroxide/STP combination prototypes would do well in a clinical study, since we know both Trident Advantage and sodium stearate in the core were significantly different in our clinical studies.

<<IP sec gen.xls>>  
Samantha



please don't print this e-mail unless you really need to.

Tuesday, May 01, 2007 AOL: WKAAllen1

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**% Stain Reduction After 7 Days of Simulated Chewing - Bottom vs Total Teeth - Test 1**

